

CY 2016 CDER Breakthrough Therapy Calendar Year Approvals

Data as of March 31, 2016

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 202570	SUPPLEMENT-16	XALKORI	CRIZOTINIB	PF PRISM CV	11-Mar-2016	Treatment of patients with non-small cell lung cancer whose tumors are ROS-1 positive
NDA 207103	SUPPLEMENT-2	IBRANCE	PALBOCICLIB	PFIZER INC	19-Feb-2016	Treatment of hormone receptor (HR)-positive, HER2-negative advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy
NDA 208261	ORIGINAL-1	ZEPATIER	GRAZOPREVIR AND ELBASVIR	MERCK SHARP AND DOHME CORP	28-Jan-2016	Treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infection in adults